Elite

Multiple Aesthetic Treatment System

User Manual

Please read this manual completely and follow the instructions carefully. The words DANGER, WARNING and NOTICE have special meanings and should be read carefully.

⚠ DANGER
The safety and/or health of the patient, user or third parties are at risk.
Observe this warning in order to avoid lesions to the patient, user or third parties.

⚠ WARNING
Information related to the purpose of this device or accessory.

⚠ NOTICE
Information on the maintenance of the device or accessory.

SYMBOLS

- Scroll through the options
- Scroll through the options
- Selecciona — Select
- See user manual
- Type B equipment

INDICATIONS

The Elite is an equipment used in the treatment of Acne, Alopecia, Bio-stimulation, Lymphatic drainage, Cinderella effect, Expression wrinkles, Dark spot, Dark circles under the eyes, Hydration, Illumination, Collagen stimulation, Postoperative, Cellulitis, Stretch marks, Localized fat and Micropigmentation.

This equipment provides energy by means of blue and amber LEDs, with wavelengths of 470 nm and 590 nm, respectively, and red and infrared laser diodes, with wavelengths of 660 nm and 808 nm, respectively.

SAFETY - IMPORTANT PRECAUTIONS

⚠ **DANGER**
Only aesthetic professionals should use this equipment
(doctors, biomedicians, technical and postgraduate estheticians and physiotherapists).

⚠ **DANGER**
The use of laser technology implies in protection through the use of safety goggles
by all those present where the laser application session is taking place.

- Do not allow the equipment to be submerged;
- Never look directly at the emitted laser light and never direct it to anyone;
- Reflective surfaces may reflect the laser beam towards the eyes;
- Never radiate tumor processes directly. The laser can stimulate them;
- Do not radiate the beam on women who are less than three months pregnant;
- The equipment should be electrically connected to ground;
- Place the equipment in a safe place, preventing it from being subjected to shock and vibration;
- Do not use abrasive solutions for cleaning.

CONTRAINDICATIONS

⚠ **WARNING**
There are no absolute contraindications; however, the examples below
should be considered inappropriate.

- Pregnant women or nursing mothers;
- Patients with an episode of skin cancer in the radiated region;
- Glaucoma patients;
- Cataracts not under medical supervision.

LIST OF COMPONENTS

- Elite Unit;
- Carrying case;
- 2 green safety goggles;
- 1 safety goggles with elastic (patient);
- User manual and warranty term.
- A/C Cable.

FRONT PANEL

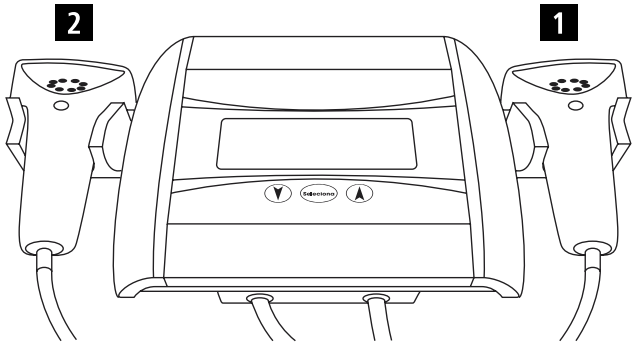
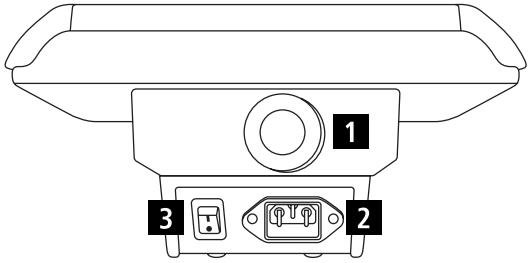


Figure 1

- **Buttons** ▼ **and** ▲ **:** used to scroll through the options of the program;
- **Button** Seleciona**:** confirms the selected options;
- **Handpiece 1 :** It has eight amber Leds and two infrared lasers.
  This handpiece will be identified as Amber LED/Infrared Laser;
- **Handpiece 2 :** It has eight blue leds and two red lasers.
  This handpiece will be identified as Blue LED/Red Laser.

BACK PANEL



- **Fan 1 :** Location of air outlet - must not be obstructed;
- **A/C Inlet 2 :** Location of A/C cable inlet;
- **On/Off Button 3 :** Turns the unit on and off.

Figure 2: Back Panel

ACNE VULGARIS

Acne (acne vulgaris) is an inflammatory disease of the pilosebaceous unit, which consists of hair and the sebaceous gland. It appears on the face and upper part of the thorax, regions where the sebaceous gland is more active. Comedones (blackheads), papules and pustules (pimples) and nodules (internal pimples).

There are many factors responsible for acne. One of them is the individual predisposition, which may or may not be inherited from the parents. With the production of sexual hormones, especially male hormones, the sebaceous gland increases its production. This sebum binds with keratin in the skin hair orifice forming a compact mass, the comedone, which is sometimes invisible to the naked eye. Some bacteria that inhabit the skin, especially Propionibacterium acnes, multiply due to the abundant supply of sebum, causing an inflammatory response that leads to the formation of pimples and acne nodules.

As a normal part of the metabolism process, the bacteria Propionibacterium acnes produces porphyrin, especially photoporphyrin and photosensitive coporphyrin Photosensitivity is a property of the molecules that absorb energy in the form of light in a certain region of the spectrum. This energy is used to cause chemical reactions in cells and tissues.

Several treatments are proposed to prevent this disease. The most conventional ones (soaps, gels with exfoliating and drying substances and oral antibiotics) control the disease, but after its suspension there is a great chance of the symptoms returning.

Phototherapy with Low Power Laser is gaining an important space among these treatments because it does not cause side effects.

SPOTS AND DARK CIRCLES

The skin has carbon molecules in its composition. These molecules are bound together sequentially in bivalent bonds with Hydrogen molecules to form long spirals grouped according to electrical affinity. The agglutination of these carbon structures form chromophores (energy absorbing substances) and cause the esthetic aspect of darkening or spots in the region of higher incidence.

Despite the existence of chromophores sensitive to other wavelengths, the action of Blue Light is directly related to the oxidation of porphyrins (wavelength of 415 nm); it is therefore considered a non-melanin action.

These extremely reactive substances remove electrons from the molecules of the Hydrogen bridges, breaking the carbon conjugation and producing simple compounds (with smaller structures).

These compounds with smaller carbon chains have their energy (Light) absorption capacity reduced and consequently have their capacity to reflect Light increased, creating the esthetic effect of whitening. It is important to emphasize that the method is biological, of known physiology, uses light within the visible spectrum and does not cause loss of substance or exfoliation of the region There is no permanent change of the tissue structure and the presence of heat is not enough to cause burns or any discomfort.

EXPRESSION MARKS

As the region chosen receives the incidence of Blue Light (470 nm), the production of free radicals is stimulated (reactive oxygen species) from melanin compounds.

These reactive Oxygen species have affinity for the Hydrogen molecule present in water. Therefore, the free Oxygen reacts with Hydrogen from the water to produce hydrolysis (water break) and consequent formation of free ions that will adhere to the wall of the cytoplasmic membrane of tissues.

These free ions will notably bond with Oxygen molecules and stimulate the presence of water in the region, creating a change in the surface tension of the skin with esthetic effect of tissue expansion, reducing eventual skin folds and expression wrinkles.

The expansion of the tissues by stimulation of the presence of water helps prevent agglutination of pigments with the ability to absorb light, optimizing the whitening esthetic effect since the carbon compounds will be more spaced, favoring the reflection of light with whitening effect. In another way, the stimulation of the presence of water also favors the esthetic whitening effect since it is known that substances solubilized in water absorb less light and reflect more.

PROGRAMMING THE NUMBER OF SESSIONS

6-8 sessions from the chosen protocol and one maintenance session every 60-90 days is recommended.

OPERATING INSTRUCTIONS

Installation
This unit has a full range power supply (90-240VAC). To turn the unit on, use the on/off switch located on the back panel.

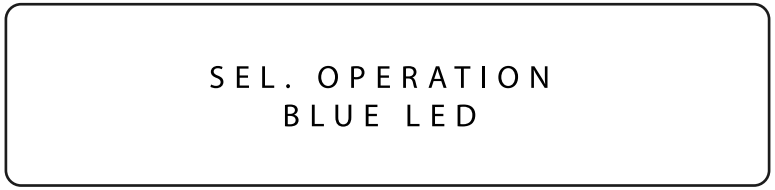
PREMILINARY PROCEDURES

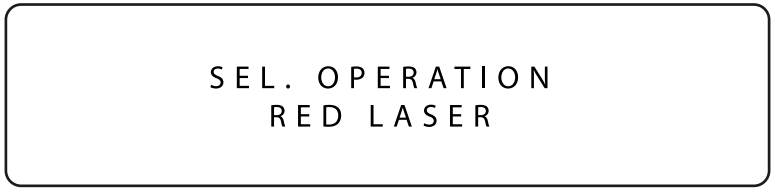
After turning the unit on, a self-test is conducted in order for the equipment to check all its internal software configurations. Then the initial screens will appear with name of the equipment, version, serial number and time of use.

The following screen will be shown. Press ▼ or ▲ to change the current selection, and Seleciona to confirm.

Entering SETUP mode

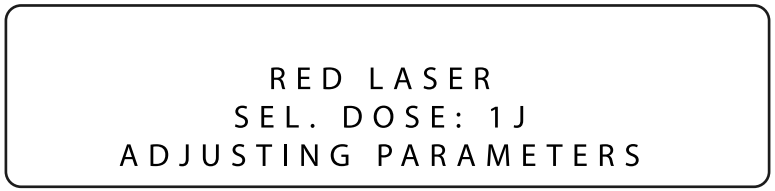
After entering the SETUP mode, press ▼ or ▲ to select between Blue LED, Red Laser, Infrared Laser, Amber LED, Body Aesthetic or Facial Aesthetic. Press Seleciona to confirm.





Red Laser Mode

After confirming the Red Laser mode the next screen allows the dosage setting. The dosage can be varied between 1 J, 2 J or 3 J. Press ▼ or ▲ to select and Seleciona to confirm.



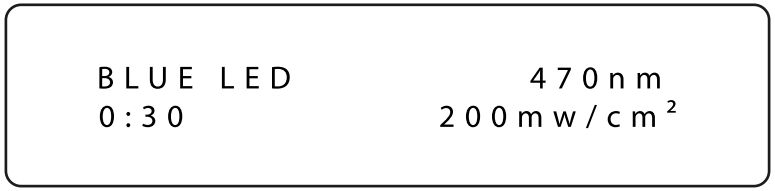
After setting the dose, the screen will appear as follows:

An energy counter is shown on the bottom left side and a fluency counter on the bottom right side.

Blue LED Mode

After confirming the Blue LED mode the next screen allows the setting of the time. The time can be adjusted from 30 seconds to 3 minutes with 30s intervals. Press ▼ or ▲ to select and Seleciona to confirm.

After setting the time, the screen will appear as follows:



The display shows a countdown timer on the bottom left side and the power density on the bottom right side.

Infrared Laser Mode

After confirming the Infrared Laser mode the next screen allows the dosage setting. The dosage can be varied between 1 J, 2 J or 3 J. Press ▼ or ▲ to select and Seleciona to confirm.

After selecting the dose, the screen will appear as follows:

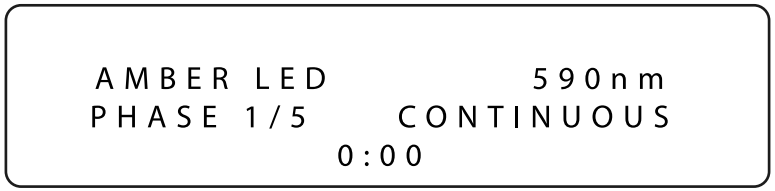
An energy counter is shown on the bottom left side and a fluency counter on the bottom right side.

Amber LED Mode

After confirming the Amber LED mode, the unit display will show the following screen:

Press Seleciona to confirm. Press the button located on the Amber LED/Infrared Laser handpiece to activate the light.

The screen will appear as follows:



To interrupt the application cycle, press the button on the Amber LED/Infrared Laser handpiece.

Body Aesthetic or Facial Aesthetic

Confirming this function allows the selection of the following pre-programmed therapies: Acne, Alopecia, Bio-stimulation, Lymphatic drainage, Cinderella effect, Expression wrinkles, Dark spot, Dark circles under the eyes, Hydration, Illumination, Collagen stimulation, Postoperative, Cellulitis, Stretch marks, Localized fat and Micropigmentation.

Press ▼ or ▲ to scroll through the therapy options. Press Seleciona to confirm the selection. To cancel and return to the previous menu, select the "Return" option and press .

The Body Aesthetic screen can be seen below:

Press ▼ or ▲ to scroll through the therapy information. Press Seleciona to confirm the selection.

After confirming the therapy, select the dosage or the time of operation, depending on the light source: LED or Laser. Press ▼ or ▲ to select and confirm by pressing Seleciona .

After finishing an application, select the next step between the options:

```
SELECT OPTION
>> NEXT AREA
   NEXT LEVEL
   CONCLUSION
```

Next Area: repeats the same light application.
Next Level: goes to the next light application.
Conclusion: ends the application and returns to the Main Menu.

Entering OPERATION mode
This screen shows the last parameters configured in the Red Laser, Infrared Laser, Blue LED and Amber LED modes. After the end of each cycle, the fan in the handpiece will remain on for about 5 minutes to cool the lighting system.

> ⚠ **NOTICE**
> The unit should only be turned off after the handpiece fan turns off.

> ⚠ **WARNING**
> Only activate the handpiece when directed to the treatment area.

> ⚠ **WARNING**
> In the case of power failure, the system will restart automatically, returning to stand-by state. It is necessary to press the handpiece button to activate the light.

PREVENTIVE MAINTENANCE

The unit must be disconnected from the electrical outlet before cleaning it in order to avoid exposing the user to electric shocks.
Clean the unit with a soft cloth dampened in 70 % alcohol.

> ⚠ **NOTICE**
> Do not allow liquids to flow into the unit through the air inlet/outlet holes. This may permanently damage the unit.

STORAGE AND TRANSPORT

Store the equipment in a cool and dry place, away from dust, moist, chemical products and cleaning agents.

TECHNICAL SPECIFICATIONS

- **Electrical Characteristics:**
  Operating Voltage: 90 V to 240 V

  Blue LED Emitter:
  - Wavelength: 470 nm

  Amber LED Emitter:
  - Wavelength: 590 nm

  Infrared Laser Diode:
  - Wavelength: 808 nm
  - Power: 100 mW

  Red Laser Diode:
  - Wavelength: 660 nm
  - Power: 100 mW

- **Electrical Power:** 60 W

WARRANTY

A. The equipments manufactured and/or sold by DMC have a warranty of 24 (twenty-four) months, as from the date of purchase, against manufacturing effects.

B. The warranty covers only manufacturing defects or defects of materials used in the manufacture of the products. The warranty does NOT cover shipment expenses.

C. The warranty is automatically canceled in the case of electrical abuse, physical abuse, if the parts are changed, or in the occurrence of applications different from those for which the equipment was developed.

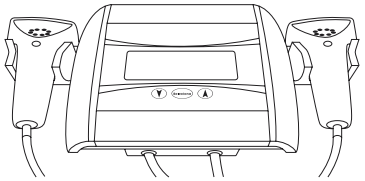
D. In the case of equipment repaired outside the warranty period, it will only be extended to the replaced components.

E. The most common causes of defects resulting from physical shocks to the equipment, cases where the warranty is canceled.

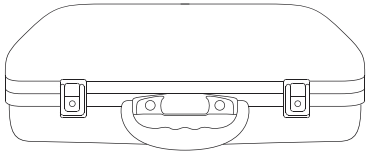
F. DMC is not responsible for personal or material damages resulting from the undue use of the equipments it produces and/or sells, and the user is responsible for providing safety measures in order to avoid such occurrences.

G. The responsibility of DMC regarding the use of the equipment and its consequences is limited to the replacement value of the equipment.

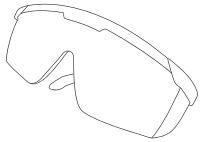
CHECKLIST



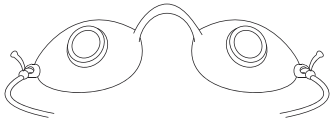
Elite Unit



Carrying Case



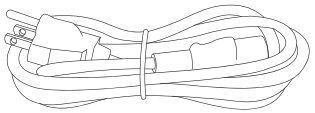
2 Green safety goggles



1 Safety goggles with elastic (patient)

Warranty Term

User Manual



A/C Cable

DMC EQUIPAMENTOS LTDA
Rua Sebastião de Moraes, 831 - Jardim Alvorada
São Carlos/SP CEP [Zip Code] 13562-030
CNPJ 02.827.605/0001-86
ANVISA Registration: 80030810090
Tech. Officer Renaldo Massini Jr. CREA 0601706815
Technical Name: Multiple Use Aesthetic Laser System

Technical Support:
DMC EQUIPAMENTOS LTDA
Telephone: +55 (16) 2107-2323 - Fax +55 (16) 2107-2320

21-MAN-113/1 Rev.: 02 Data de Revisão: 06/03/2012